

Claims

- Sub B17
1. A catheter having an elongate configuration with a proximal end and a distal end, the catheter comprising:
an outer tube having an elongate configuration and a first lumen;
an inner tube disposed in the first lumen of the outer tube and having a second lumen extending between the proximal end and the distal end of the catheter;
portions of the inner tube defining a first fluid flow path extending along the second lumen between the proximal end and the distal end of the catheter;
portions of the outer tube and the inner tube defining a second flow path extending between the first tube and the second tube; and
a plurality of hollow fibers providing fluid communication between the first fluid flow path and the second fluid flow path.
2. The catheter recited in Claim 1, wherein:
each of the hollow fibers has a proximal end and a distal end;
the distal end of each of the hollow fibers has a fixed relationship with the distal end of the inner tube; and
the proximal end of each of the hollow fibers has a fixed relationship with the distal end of the outer tube.
- Sub B2
3. The catheter recited in Claim 2, wherein the inner tube has properties for moving relative to the outer tube to vary the configuration of the hollow fibers extending between the inner tube and the outer tube.

- 2
4. The catheter recited in Claim 3, wherein:

portions of the inner tube define a taper, the inner tube being axially movable to bring the portions of the inner tube into sealing proximity with the hollow fibers.

5. The catheter recited in Claim 1 further comprising:
a cap disposed over the distal ends of the inner tube and the hollow fibers.

6. The catheter recited in Claim 1, further comprising:
a seal tube disposed inwardly of the proximal end of the hollow fibers and forming a seal with the distal end of the outer tube and the proximal ends of the hollow fibers.

7. The catheter recited in Claim 6, wherein the seal tube extends proximally of the proximal end of the hollow fibers.

8. The catheter recited in Claim 4, further comprising:
a seal tube disposed inwardly of the proximal end of the hollow fibers and forming a seal with the distal end of the outer tube and the proximal end of the hollow fibers; and
the portions of the inner tube which define the taper are axially movable relative to the outer tube in the sealing engagement with the hollow fibers.

9. The catheter recited in Claim 1, wherein the hollow fibers are adapted to receive a heat exchange fluid from the first flow path and to release the heat exchange fluid into the second flow path.

10. The catheter recited in Claim 3, further comprising:
a seal tube disposed between the hollow fibers and the inner tube and having an inner diameter greater than the outer diameter of the inner tube, but sufficiently close to the outer

diameter of the inner tube to form a liquid seal between the seal tube and the inner tube by capillary action.

11. The catheter recited in Claim 10, wherein:
portions of the inner tube define a taper, the inner tube being axially movable to bring the portions of the inner tube into sealing proximity with the distal end of the seal tube.
12. The catheter recited in Claim 5, further comprising:
a coating of insulation covering the cap at the distal end of the catheter.
13. The catheter recited in Claim 1, wherein the hollow fibers are adapted to receive a heat exchange fluid from the second flow path and to release the heat exchange fluid into the first flow path.
14. A method for making a heat exchange catheter, comprising the steps of:
providing a first tube having a first lumen extending between a proximal end and a distal end;
inserting a second tube into the lumen of the first tube, the second tube having a second lumen;
connecting a plurality of hollow fibers in fluid communication with a first flow path extending along the second lumen of the second tube, and a second flow path extending along the first lumen of the first tube outwardly to the second tube; and
insuring that the second tube is at least one of axially and rotationally movable relative to the first tube to vary the configuration of the hollow fibers in order to facilitate heat exchange with the heat exchange catheter.
15. The method recited in Claim 14, wherein the insuring step includes the steps of:

moving the second tube distally relative to the first tube to change the hollow fibers to a low profile state; and

moving the second tube proximally relative to the first tube to change the hollow fibers to a high profile state.

16. The method recited in Claim 14, wherein the connecting step further comprises the steps of:

forming the hollow fibers in a stack having a generally planar configuration;
wrapping the hollow fibers stack around the second tube; and
inserting the hollow fibers into the distal end of the first tube.

17. The method recited in Claim 14, further comprising the steps of:
fixing to the proximal end of the first tube a Y-connector having fluid communication with the second flow path.

18. The method recited in Claim 17, further comprising the steps of:
attaching a locking device to the Y-connector, the locking device being operable between a first position permitting movement of the second tube relative to the first tube, and a second position inhibiting movement of the second tube relative to the first tube.

19. The method recited in Claim 16, further comprising the step of:
potting the hollow fiber stack to form an end seal tapered radially inwardly to inhibit formation of stagnant flow regions around the fibers of the stack.

20. A method for operating a heat exchange catheter within a body conduit containing a body fluid, the method comprising the steps of

inserting into the body conduit the heat exchange catheter with an inner tube disposed within an outer tube to define a first flow path interiorly of the inner tube and a second flow path between the inner tube and the outer tube, and a plurality of hollow fibers disposed in fluid communication between the first flow path and the second flow path; and

creating a flow of heat exchange fluid by introducing the heat exchange fluid into one of the first flow path and the second flow path.

21. The method recited in Claim 20, wherein the inserting step includes the step of pushing the inner tube distally relative to the outer tube to provide the hollow fibers with a lower profile.

22. The method recited in Claim 20, wherein the creating step further comprises the step of reciprocating the inner tube relative to the outer tube to create a continuous movement of the hollow fibers in order to facilitate heat exchange between the hollow fibers and the body fluid.

23. The method recited in Claim 20, further comprising the steps of:

removing the catheter from the body conduit, and prior to the removing step, pushing the inner tube distally relative to the outer tube to provide the hollow fibers with a lower profile.

24. The method recited in Claim 20, wherein prior to the inserting step the method comprises the steps of:

providing a sheath outwardly of the outer tube and movable between a first position spaced from the hollow fibers and a second position proximate to the hollow fibers; and

moving the sheath to the second position and over the hollow fibers to maintain the fibers in a low profile state.

25. The method recited in Claim 24, further comprising the steps of after the inserting step, moving the sheath from the second position to the first position.
26. The method recited in Claim 25, further comprising the step of after the first moving step, moving the sheath from the first position to the second position and withdrawing the catheter.
27. The method recited in Claim 20, wherein the heat exchange fluid is a cooling fluid.
28. A heat exchange catheter, including:
an elongate shaft extending along an axis between a proximal end a distal end;
first portions of the shaft defining an inlet lumen extending between the proximal end and the distal end of the shaft;
second portions of the shaft defining an outlet lumen;
a first manifold in fluid communication with the inlet lumen at the distal end of the shaft;
a second manifold in fluid communication with the outlet lumen of the shaft;
a plurality of hollow fibers disposed to extend between the first manifold and the second manifold in fluid communication with the inlet lumen and the outlet lumen; and
the catheter being adapted to receive a heat exchange fluid at the proximal end of the inlet lumen, and to direct the heat exchange fluid through the hollow fibers to exchange heat through the hollow fibers.
29. The heat exchange catheter recited in Claim 28, wherein the first manifold is disposed distally of the second manifold.

30. The heat exchange catheter recited in Claim 29, wherein the outlet lumen is disposed outwardly of the inlet lumen.
31. The heat exchange catheter recited in Claim 28, wherein the shaft comprises:
an inner tube defining the input lumen; and
an output tube concentric with the input tube and defining with the input tube the output lumen.
32. The heat exchange catheter recited in Claim 31, wherein:
the first tube has a fixed relationship with the first manifold;
the second tube has a fixed relationship with the second manifold; and
the first tube is axially movable relative to the second tube to vary the configuration of the hollow fibers.
33. The heat exchange catheter recited in Claim 32, wherein the first tube is movable axially of the second tube to separate the first manifold and the second manifold, and to place the hollow fibers in a generally straight, parallel relationship.
34. The heat exchange catheter recited in Claim 28, wherein the heat exchange fluid is a liquid.
35. A catheter adapted to exchange heat with a body fluid flowing through a body conduit, the catheter comprising:
a shaft having an axis extending between a proximal end and a distal end, the shaft having an input lumen and an output lumen;
a plurality of hollow fibers defining a heat exchange region of the shaft and collectively defining an outer surface of the heat exchange region;

the input lumen of the shaft coupled to the hollow fibers of the heat exchange region at a first location, the output lumen of the shaft being coupled to the hollow fibers of the heat exchange region at a second location such that a heat exchange fluid introduced into the input lumen will enter the hollow fibers of the heat exchange region at the first location and will exit the hollow fibers of the heat exchange region at the second location through the output lumen.

36. The catheter recited in Claim 35, wherein the body fluid flows in a first direction through a body conduit and the heat exchange fluid flows through the hollow fibers in a second direction opposite to the first direction.

37. The catheter recited in Claim 35, further comprising:
a clot inhibiting coating covering the hollow fibers.

38. The catheter recited in Claim 36, further comprising:
a clot snare disposed in the first direction from the heat exchange region.

39. The catheter recited in Claim 37, wherein portions of each hollow fiber defines a multiplicity of micro pores and the coating is formed by a clot inhibiting chemical included in the heat exchange fluid and leechable through the micro pores of the fibers.

40. A method for exchanging heat with a body fluid in a body conduit, comprising the steps of:

introducing into the body conduit a catheter having an inlet lumen and an outlet lumen;

providing the catheter with a first cavity in heat transfer relationship with a body fluid in the body conduit;

introducing a heat exchange fluid into the inlet lumen and into the first cavity;
exchanging heat between the heat exchange fluid and the body fluid in the body conduit;

removing the heat exchange fluid from the first cavity through the outlet lumen; and
during the providing step, providing the catheter with a plurality of hollow heat exchange fibers each extending in fluid communication with the inlet lumen and the outlet lumen, the heat exchange fibers collectively defining the first cavity in heat transfer relationship with the body fluid in the body conduit.

41. The method recited in Claim 40, wherein the second introducing step includes the step of introducing the heat exchange fluid into the hollow fibers.

42. A catheter having an elongate configuration with a proximal end and distal end, comprising:

an operative area of the catheter sized and configured for disposition in a vessel containing blood flowing in a particular direction, the operative area being adapted to perform a predetermined function and the blood in the vessel having a tendency to form blood clots; and

a snare disposed in the particular direction from the operative area and being operable from the proximal end of the catheter to move from a low-profile state facilitating insertion of the catheter into the vessel, and a high-profile state facilitating capture of any blood clots.

43. The catheter recited in Claim 42, wherein the snare is disposed distally of the operative area of the catheter.

44. The catheter recited in Claim 42, wherein the operative area includes a heat exchange region of the catheter.

45. The catheter recited in Claim 44, wherein the heat exchange region is a heat receiving region of the catheter.
46. The catheter recited in Claim 42, wherein the snare includes:
a plurality of elongate filaments each having a first end attached to the operative region of the catheter and a second end.
47. The catheter recited in Claim 46, wherein the second ends of the filaments are unattached.
48. The catheter recited in Claim 46, wherein:
the catheter further comprises a cap disposed at the distal end of the catheter;
the second ends of the filaments are attached to the cap; and
movement of the cap relative to the operative region of the catheter changes the profile of the snare.
49. The catheter recited in Claim 48, further comprising:
a shaft attached to the cap and extending to the proximal end of the catheter; whereby
the profile of the snare is changed by movement of the shaft relative to the operative region of the catheter.
50. The catheter recited in Claim 42, wherein the filaments are formed of wire.
51. The catheter recited in Claim 50, wherein the wire filaments include a nickel titanium alloy.

52. A heat exchange catheter having an elongate configuration and extending between a proximal end and a distal end, the catheter being adapted for cooling the blood of a patient, comprising:

- a heat exchange region of the catheter;
- a plurality of fibers included in the heat exchange region, with each of the fibers having a hollow configuration and being adapted to receive a heat exchange fluid; and
- a coating disposed on the outer surface of the fibers to inhibit the formation of blood clots on the cooled fibers.

53. The heat exchange catheter recited in Claim 52, further comprising a chemical included in the coating and having characteristics for inhibiting the formation of the blood clots.

54. The heat exchange catheter recited in Claim 53, wherein the chemical includes heparin.

55. The heat exchange catheter recited in Claim 53, wherein:

- each of the fibers includes a multiplicity of micro pores extending between the hollow interior of the fibers and the outer surface of the fibers; and
- the chemical is included in the heat exchange fluid and leached with the heat exchange fluid through the micro pores to coat the outer surface of the fibers.

56. The method recited in Claim 20 further comprising the step of:
moving the inner tube relative to the outer tube to change the profile of the hollow fibers.

57. The method recited in Claim 20, wherein the creating step includes the step of:

providing a heat exchange fluid in the form of a liquid.

58. The method recited in Claim 20, wherein the creating step includes the step of:
providing a heat exchange fluid in the form a gas.

59. The method recited in Claim 20, wherein the creating step includes the step of:
heating the heat exchange fluid prior to introducing the heat exchange fluid into the
catheter.

60. The method recited in Claim 20, wherein the creating step includes the step of:
cooling the heat exchange fluid prior to introducing the fluid into the catheter.

61. The heat exchange catheter recited in Claim 28, wherein the heat exchange fluid is a
gas.

62. The heat exchange catheter recited in Claim 28, wherein the heat exchange fluid is a
cooling fluid.

63. The heat exchange catheter recited in Claim 28, wherein the heat exchange fluid is a
heating fluid.

ADD
#1